DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-05-14

December 8, 2004

Jose E. Rincon, President/Owner
Lamar Seafood Corporation
10545 NW 29th Terrace
Miami, Florida 33172-2531

Dear Mr. Rincon:

On October 6-8, 2004, we inspected your seafood processing facility located at the above listed address. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) and the Good Manufacturing Practices in Manufacturing, Packaging, or Holding Human Food (21 CFR part 110). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly, your refrigerated unpasteurized crabmeat is adulterated, in that the crabmeat has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

At the close of the inspection, you were issued a Form FDA 483 which lists a number of inspectional observation which include, but are not limited to, the following:

1. You must implement the monitoring procedures that you have listed in your HACCP plan, to comply with 21 CFR 123.6 (b). However, your firm failed to follow the monitoring procedures of taking the internal temperature of products and checking the adequacy of cooling media at the receiving and storage critical control points to control pathogen growth and toxin formation as listed in your HACCP plan for unpasteurized crabmeat. Additionally, no monitoring records were maintained and your process monitoring equipment is not calibrated.

2. You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However your firm failed to monitor hand washing facilities with sufficient frequency to ensure control as evidenced by the hand sink in the female employee's restroom not having hot water and a paper towel dispenser in the cooler /processing area not having paper towels.

3. You must maintain sanitation control records that, at a minimum, document monitoring and correction to comply with 21 CFR 123.11(c). However your firm failed to maintain sanitation monitoring records for the following: safety of water that comes in contact with food or food contact surfaces, or is used in the manufacture of ice; condition of food contact surfaces; prevention of cross-contamination from insanitary objects; protection of food, food packaging material, and food contact surfaces from adulteration; proper labeling and storage; control of employee health conditions and exclusion of pests required for the processing of crabmeat from May 13, 2004 until October 8, 2004.

In addition to deviations listed above, your firm continues to have several deviations from the Import Seafood HACCP regulations located at 21 C.F.R. 123.12. For example, your foreign processor's HACCP plan fails to identify receiving as a critical control point to control specie related hazards of environmental chemical contaminants and pesticides and the foreign processor's HACCP plan for crabmeat was not signed by the most responsible individual at the processing facility.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP Regulation and the Good Manufacturing practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated without further notice. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, FDA may detain your imported seafood products without physical examination.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific steps you have taken to correct these deviations. You should include in your response documentation or other useful information that would assist us in evaluation your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your response to the Food and Drug Administration, Attention: Virginia L. Meeks, Compliance Officer, 555 Winderley Place Suite, Maitland, Florida 32571. If you have questions regarding any issue in this letter, please contact Ms. Meeks at (407) 475-4731.

Sincerely,

Emma R. Singleton
Director
Florida District